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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,985	11/18/2003	Thomas F. Fangrow JR.	ICUMM.183A	4879

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EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,985	FANGROW, THOMAS F.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/23/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgements

1. This office action is in response to the reply filed on 6/30/2006.

2. In the reply, the applicant amended claim 1 and 8. Thus, claims 1-13 remain pending.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 6/30/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

4. Claim 7 is objected to because of the following informalities: Claim 7 recites ":" in ln 2 instead of ".". The appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Douglas (6923791). Douglas discloses an injection assembly (Fig 1) for subcutaneous medication delivery with a base (100) having upper and lower sides (130, 140) with the

lower side of the base having an adhesive layer (150), the round base having an outer edge having a retaining rim (135), a base cannula (110) extending downwardly from the lower side (Fig 1), a funnel shaped port (Fig 2, 400) extending upwardly from the upper side (Fig 2) in fluid communication with the base cannula and having a septum (120) of a different material from the port positioned above the retaining rim at near the upper side that seals the port from fluid flow. An introducer cap (500, Figs 10-12) having upper and lower sides and a needle (510) extending downwardly from the lower side (Fig 10) can removably attach to the base at the retaining rim by at least two generally flat surface (Fig 11, 520) and the needle can extend through the septum and through the base cannula (Fig 10) to pierce the skin while the adhesive on the base contacts the skin (Fig 10). Furthermore, an infusion cap (200) with upper and lower sides (Fig 1) and an infusion cannula (210) extending downwardly from the lower side of the cap and an elongate flexible lumen (215) in fluid communication with the infusion cannula (Fig 9) that extends through the septum to be in fluid communication with the base cannula (Fig 2), the cap being adapted to rotation with respect to the base while engaged (Summary), and the cap being adapted to generally cover the upper side of the base and to be removably attached to the base at the retaining rim (Fig 2); and wherein both the introducer cap at the infusion cap include a substantially cylindrical portion adapted to surround the port on the base when engaged with the base (Fig 2; Fig 10).

7. Claims 8-9, 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Douglas et al (6685674). Douglas et al discloses an injection assembly (Figs 1-3) for subcutaneous medication delivery with a base (10) having upper and lower sides (Fig 1)

with the lower side of the base having an adhesive layer (12), the round base having an outer edge having a retaining rim (Fig 1, see annular projections on the sides of the base), a base cannula (22) extending downwardly from the lower side (Fig 1), a funnel shaped port (Fig 1) extending upwardly from the upper side (Fig 1) in fluid communication with the base cannula and having a septum (20) of a different material from the port positioned above the retaining rim at near the upper side that seals the port from fluid flow. An introducer cap (32) having upper and lower sides (Fig 2) and a needle (30) extending downwardly from the lower side (Fig 2) can removably attach to the base at the retaining rim by at least a generally flat surface (32, Fig 2) and the needle can extend through the septum and through the base cannula (Fig 2) to pierce the skin while the adhesive on the base contacts the skin (Fig 2). Furthermore, a low-profiled dome-shaped infusion cap (40) with upper and lower sides (Fig 3) and an infusion cannula (44) extending downwardly from the lower side of the cap and an elongate flexible lumen (50) in fluid communication with the infusion cannula (Fig 3) that extends through the septum to be in fluid communication with the base cannula (Fig 3), the cap being adapted to rotated with respect to the base while engaged (Fig 4-5), and the cap being adapted to generally cover the upper side of the base and to be removably attached to the upper side of the base (Fig 3); and wherein both the introducer cap at the infusion cap include a substantially cylindrical portion adapted to surround the port on the base when engaged with the base (Fig 2-6).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas ('791). Douglas '791 discloses the invention substantially as claimed except for expressly disclose the infusion cap has a low-profile substantially dome-shaped upper side and a generally done-shaped introducer cap. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the infusion cap has a low-profile substantially dome-shaped upper side and a generally done-shaped introducer cap because it would have been an obvious matter of design choice to have the infusion cap has a low-profile substantially dome-shaped upper side and a generally done-shaped introducer cap, since the Applicant's specification recites that the advantageous dome-shape of the infusion cap provides cover for the entire base member, thereby protecting the base member from contamination by dirt, dust, germs, or other contaminants (paragraph [0074, lns 6-8]) and Douglas '791 teaches that it is known to have an introducer cap that covers the entire base. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a infusion cap with a non-dome shape that covers the entire base member because the Applicant has not disclosed that a dome-shape provides an advantage, is used for a particular purpose, or

solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the infusion cap of Douglas '791 because the cap covers the entire base member and provides protection against contamination. Therefore, it would have been an obvious matter of design choice to modify the infusion cap of Douglas '791 to obtain the invention as specified in claims 7-13.

Response to Arguments

10. Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER